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SCIENTIFIC OPINION

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Safety evaluation of the food enzyme inulinase from the non-genetically modified *Aspergillus welwitschiae* strain NZYM-KF

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Abstract

The food enzyme inulinase (1-β-D-fructan fructanohydrolase; EC 3.2.1.7) is produced with the non-genetically modified *Aspergillus welwitschiae* strain NZYM-KF by Novozymes A/S. The food enzyme is free from viable cells of the production organism. It is intended to be used in the processing of fructo-polysaccharides for the production of fructo-oligosaccharides. Since residual amounts of total organic solids (TOS) are removed during the food manufacturing process, toxicological studies other than allergenicity were considered unnecessary and dietary exposure was not calculated. A search for the similarity of the amino acid sequence of the food enzyme to known allergens was made and two matches with tomato allergens were found. The Panel considered that the risk of allergic reactions upon dietary exposure to this food enzyme, particularly in individuals sensitised to tomato, cannot be excluded, but is expected not to exceed that of tomato. As the prevalence of allergic reactions to tomato is low, also the likelihood of such reactions to occur to the food enzyme is low. Based on the data provided, the Panel concluded that this food enzyme does not give rise to safety concerns, under the intended conditions of use.

KEYWORDS

1-β-D-fructan fructanohydrolase, EC 3.2.1.7, EFSA-Q-2015-00827, food enzyme, genetically modified microorganism, inulase, inulinase

CONTENTS

1 | INTRODUCTION

Article 3 of the Regulation (EC) No 1332/2008[1] provides definition for 'food enzyme' and 'food enzyme preparation'.

'Food enzyme' means a product obtained from plants, animals or microorganisms or products thereof including a product obtained by a fermentation process using microorganisms: (i) containing one or more enzymes capable of catalysing a specific biochemical reaction; and (ii) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods.

'Food enzyme preparation' means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

Before January 2009, food enzymes other than those used as food additives were not regulated or were regulated as processing aids under the legislation of the Member States. On 20 January 2009, Regulation (EC) No 1332/2008 on food enzymes came into force. This Regulation applies to enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids. Regulation (EC) No 1331/2008[2] established the European Union (EU) procedures for the safety assessment and the authorisation procedure of food additives, food enzymes and food flavourings. The use of a food enzyme shall be authorised only if it is demonstrated that:

- it does not pose a safety concern to the health of the consumer at the level of use proposed;
- there is a reasonable technological need;
- its use does not mislead the consumer.

All food enzymes currently on the European Union market and intended to remain on that market, as well as all new food enzymes, shall be subjected to a safety evaluation by the European Food Safety Authority (EFSA) and approval via an EU Community list.

The 'Guidance on submission of a dossier on food enzymes for safety evaluation' (EFSA, 2009a) lays down the administrative, technical and toxicological data required.

1.1 | Background and Terms of Reference as provided by the requestor

1.1.1 | Background as provided by the European Commission

Only food enzymes included in the European Union (EU) Community list may be placed on the marked as such and used in foods, in accordance with the specifications and conditions of use provided for in Article 7 (2) of Regulation (EC) No 1332/2008 on food enzymes.

Five applications have been introduced by the companies "Chr. Hansen" for the authorisation of the food enzyme endothiapepsin from a genetically modified strain of *Cryphonectria parasitica* (strain DSM 29549),"Nagase (Europa) GmbH" for the authorisation of the food enzymes L-Ascorbate oxidase from *Cucurbita pepo* and *Cucurbita moschata*, and Microbial collagenase from a genetically modified strain of *Streptomyces violaceoruber* (strain pCol); "Novozymes A/S" for the authorisation of the food enzyme inulinase from *Aspergillus niger* (strain NZYM-KF), and "Danisco US Inc." for the authorisation of the food enzyme Endo-1,3(4)-beta-glucanase from a genetically modified strain of *Bacillus subtilis* (DP-Ezm28).

Following the requirements of Article 12.1 of Regulation (EC) No 234/20113 implementing Regulation (EC) No 1331/2008, the Commission has verified that the five applications fall within the scope of the food enzyme Regulation and contain all the elements required under Chapter II of that Regulation.

1.1.2 | Terms of Reference

The European Commission requests the European Food Safety Authority to carry out the safety assessments of the food enzymes endothiapepsin from a genetically modified strain of *Cryphonectria parasitica* (strain DSM 29549), L-Ascorbate oxidase from *Cucurbita pepo* and *Cucurbita moschata*, Microbial collagenase from a genetically modified strain of *Streptomyces violaceoruber* (strain pCol); Inulinase from *Aspergillus niger* (strain NZYM-KF) and Endo-1,3(4)-beta-glucanase from a genetically modified strain of *Bacillus subtilis* (DP-Ezm28) in accordance with Article 17.3 of Regulation (EC) No 1332/2008 on food enzymes.

[1]Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on Food Enzymes and Amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97. OJ L 354, 31.12.2008, pp. 7–15.

[2]Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354, 31.12.2008, pp. 1–6.

1.2 | Interpretation of the Terms of Reference

The present scientific opinion addresses the European Commission's request to carry out the safety assessment of food enzyme inulinase from *Aspergillus niger* strain NZYM-KF.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a dossier in support of the application for authorisation of the food enzyme inulinase from *Aspergillus niger* strain NZYM-KF.

Additional information was requested from the applicant during the assessment process on 27 July 2022 and received on 06 July 2023 (see 'Documentation provided to EFSA').

Recent data identified the production microorganism as *Aspergillus welwitschiae* (Section 3.2). Therefore, this name will be used in this opinion instead of *Aspergillus niger*.

2.2 | Methodologies

The assessment was conducted in line with the principles described in the EFSA 'Guidance on transparency in the scientific aspects of risk assessment' (EFSA, 2009a) and following the relevant guidance documents of the EFSA Scientific Committee.

The 'Guidance on the submission of a dossier on food enzymes for safety evaluation' (EFSA, 2009b) as well as the 'Statement on characterisation of microorganisms used for the production of food enzymes' (EFSA CEP Panel, 2019) have been followed for the evaluation of the application. Additional information was requested in accordance with the updated 'Scientific Guidance for the submission of dossiers on food enzymes' (EFSA CEP Panel, 2021) and the guidance on the 'Food manufacturing processes and technical data used in the exposure assessment of food enzymes' (EFSA CEP Panel, 2023).

3 | ASSESSMENT

IUBMB nomenclature	Inulinase
Systematic name	1-β-D-fructan fructanohydrolase
Synonyms	Inulase; endoinulinase; 2,1-β-D-fructan fructanohydrolase
IUBMB no	EC 3.2.1.7
CAS no	9025-67-6
EINECS no	232-802-3

Inulinases catalyse the hydrolysis of (2→1)-β-D-fructosidic linkages in inulin, resulting in the generation of fructo-oligosaccharides (FOS). The food enzyme under application is intended to be used in the processing of fructo-polysaccharides for the production of FOS.

3.1 | Source of the food enzyme

The enzyme is produced with the non-genetically modified filamentous fungus *Aspergillus welwitschiae* strain NZYM-KF, which is [redacted] with the deposit number [redacted].[3] The production strain was identified as *Aspergillus welwitschiae* by phylogenetic analysis of the internal transcribed spacer region, calmodulin, β-tubulin and RNA polymerase gene sequences. [redacted].

[3]Technical dossier/Additional information July 2023/Annex A1.

3.2 | Production of the food enzyme

The food enzyme is manufactured according to the Food Hygiene Regulation (EC) No 852/2004,[4] with food safety procedures based on Hazard Analysis and Critical Control Points, and in accordance with current Good Manufacturing Practice.[5]

[redacted].[7]

The Panel considered that sufficient information has been provided on the manufacturing process and the quality assurance system implemented by the applicant to exclude issues of concern.

3.3 | Characteristics of the food enzyme

3.3.1 | Properties of the food enzyme

The inulinase is a single polypeptide chain of [redacted] amino acids.[8] The molecular mass of the mature protein, calculated from the amino acid sequence, is around [redacted] kDa.[9] The food enzyme was analysed by sodium dodecyl sulfate-polyacrylamide gel electrophoresis. A consistent protein pattern was observed across all batches. The gel showed a protein migrating between the marker proteins of [redacted] and [redacted] kDa in all batches, consistent with the calculated mass of the food enzyme.[10] The food enzyme was tested for protease, glucoamylase, β-glucanase, α-amylase and lipase activities. Only protease, glucoamylase and β-glucanase activities were detected. No other enzymatic activities were reported.[11]

The in-house determination of inulinase activity is based on the hydrolysis of inulin (reaction conditions: pH 4.7, 50°C, 20 min), quantifying the release of reducing carbohydrates by means of a colorimetric assay measured spectrophotometrically at 405 nm. The enzyme activity is expressed in inulinase units (INU)/g. One unit is equivalent to the amount of enzyme that produces 1 µmol of reducing carbohydrates per minute under the conditions of the assay.[12]

The food enzyme has a temperature optimum between 40°C and 60°C (pH 6.0) and a pH optimum around pH 5.0 (37°C). Thermostability was tested after a pre-incubation of the food enzyme for 30 min at different temperatures (pH 6.0). The enzyme activity decreased above 65°C, showing no residual activity above 72°C after 30 min of pre-incubation.[13]

3.3.2 | Chemical parameters

Data on the chemical parameters of the food enzyme were provided for three batches used for commercialisation (Table 1).[14] The mean total organic solids (TOS) was 18.9% and the mean enzyme activity/TOS ratio was 23.8 INU/mg TOS.

[4]Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of food additives. OJ L 226, 25.6.2004, pp. 3–21.
[5]Technical dossier/p. 45 and Annex 4.
[6]Technical dossier/pp. 19–20, 45–52.
[7]Technical dossier/pp. 34, 46, 48, 50 and Annexes: 1.06, 5.
[8]Technical dossier/p. 30 and Additional data July 2023/Annex A4.
[9]Technical dossier/p. 30 and Additional data July 2023/Annex A4.
[10]Technical dossier/p. 32 and Additional data July 2023/Annex A7.
[11]Technical dossier/pp. 39–40 and Annexes: 2.02–2.06.
[12]Technical dossier/pp. 11, 36–37 and Annex 2.01.
[13]Technical dossier/pp. 12, 38–39 and Annex 7.
[14]Technical dossier/pp. 31, 58, Annexes: 1.01–10.3 and Additional data July 2023/Annex A8.

TABLE 1 Composition of the food enzyme.

Parameters	Unit	Batches		
		1	2	3
Inulinase activity	INU/g[a]	3900	4770	4650
Protein	%	9.9	12.2	10.8
Ash	%	1.3	4.5	1.8
Water	%	83.6	73.1	79.1
Total organic solids (TOS)[b]	%	15.1	22.4	19.1
Activity/mg TOS ratio	INU/mg TOS	25.8	21.3	24.3

[a]INU: inulinase activity (see Section 3.3.1).
[b]TOS calculated as 100% – % water – % ash.

3.3.3 | Purity

The lead content in all batches was below 1 mg/kg which[15] complies with the specification for lead as laid down in the general specifications for enzymes used in food processing (FAO/WHO, 2006). In addition, arsenic, cadmium and mercury contents were below the limit of detection (LoD) of the employed methods.[16,17]

The food enzyme complies with the microbiological criteria for total coliforms, *Escherichia coli* and *Salmonella* as laid down in the general specifications for enzymes used in food processing (FAO/WHO, 2006).[18] No antimicrobial activity was detected in any of the tested batches.[19]

Strains of *Aspergillus*, in common with most filamentous fungi, have the capacity to produce a range of secondary metabolites (Frisvad et al., 2018). The presence of fumonisin B2 and ochratoxin A was examined in the three food enzyme batches and both were below the LoD of the applied analytical methods.[20,21]

The Panel considered that the information provided on the purity of the food enzyme was sufficient.

3.3.4 | Viable cells of the production strain

The absence of viable cells of the production strain in the food enzyme was demonstrated in three independent batches analysed in triplicate. [redacted]. No colonies were produced. A positive control was included.

3.4 | Toxicological data[22]

No toxicological studies were provided for the inulinase food enzyme produced with *A. welwitschiae* NZYM-KF. Instead, the applicant argued that the assessment could be based on toxicological data from another food enzyme, an α-galactosidase produced with an ancestor of the production strain *A. welwitschiae* NZYM-KF and provided a battery of toxicological tests of that α-galactosidase. However, as conventional mutagenesis was applied in the development of *A. welwitschiae* NZYM-KF from its ancestor, the α-galactosidase was not considered acceptable as a substitute of the inulinase under assessment and therefore the toxicological tests provided were not considered.

However, taking into account that the residual amounts of food enzyme–TOS is negligible (see Section 3.5.1), the Panel considered that toxicological tests were not needed for the assessment of this food enzyme.

3.4.1 | Allergenicity

The allergenicity assessment considers only the food enzyme and not carriers or other excipients that may be used in the final formulation.

[15]Technical dossier/pp. 11, 33, 35, 58 and Annex 1.04.
[16]Technical dossier/pp. 11, 33, 35, 58 and Annex 1.04.
[17]LoDs: Pb = 1 mg/kg; As = 0.3 mg/kg; Cd, Hg = 0.05 mg/kg each.
[18]Technical dossier/pp. 11, 35, 58/Annexes: 1.07–1.11.
[19]Technical dossier/pp. 11, 35, 58 and Annex 1.07.
[20]Technical dossier/pp. 11, 33, 3, Annex 1.05 and Additional data July 2023.
[21]LoDs: fumonisin B2, ochratoxin A = 0.0003 mg/kg each.
[22]Technical dossier/p. 57.

The potential allergenicity of the enzyme produced with the non-genetically modified *A. welwitschiae* strain NZYM-KF was assessed by comparing its amino acid sequence with those of known allergens according to the 'Scientific opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed of the Scientific Panel on Genetically Modified Organisms' (EFSA GMO Panel, 2010). Using higher than 35% identity in a sliding window of 80 amino acids as the criterion, two matches were found for *β*-fructofuranosidase (Sola l 2.0101 and Sola l 2.0201) produced by tomatoes (*Solanum lycopersicum*) and described as minor allergens.

No information was available on oral and respiratory sensitisation or elicitation reactions of this enzyme. The sequence homology of this enzyme with two sequences of tomato indicates a potential cross-reactivity of the enzyme with the allergen from tomato. Tomato is one of the most frequently consumed vegetables worldwide. Although a number of specific allergen proteins has been identified in tomato, tomato allergy is rare (Asero et al., 2008, 2010).

Aspergillus species are known to cause respiratory allergy (Kauffman et al., 1984; Kurup et al., 2000; Shen et al., 2000). However, several studies have shown that individuals respiratorily sensitised can ingest corresponding allergens without acquiring clinical symptoms of food allergy (Armentia et al., 2009; Cullinan et al., 1997; Poulsen, 2004).

[redacted] that may cause allergies or intolerances (listed in the Regulation (EU) No 1169/2011[23]) is used as raw material. However, during the fermentation process, this product will be degraded and utilised by the microorganisms for cell growth, cell maintenance and production of enzyme protein. In addition, the fungal biomass and fermentation solids are removed. Taking into account the fermentation process and downstream processing, the Panel considered that potentially allergenic residues from this source are not expected to be present in the food enzyme.

The Panel considered that a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, in particular for individuals sensitised to tomatoes, but it will not exceed that from consumption of tomatoes and will be low.

3.5 | Dietary exposure

3.5.1 | Intended use of the food enzyme

The food enzyme is intended to be used in the processing of fructo-polysaccharides for the production of FOS at an actual use level of [redacted],[24] corresponding to 0.42–3 mg TOS/kg inulin dry matter.

In this food manufacturing process, the food enzyme is added to inulin syrup, which has 10%–70% dry solids and is extracted from plant materials containing inulin (e.g., chicory, Jerusalem artichoke, garlic, onion etc.).[25] The hydrolysis by inulinase releases FOS. The downstream process involves ion exchange and/or activated carbon filtration,[26] which are expected to remove the food enzyme–TOS from the final FOS products.

To establish the extent of TOS removed during the inulin manufacturing process, [redacted][27] The Panel accepted the amino acids as a suitable proxy for the food enzyme–TOS for this process. Consequently, these data were considered by the Panel as sufficient to confirm the absence of TOS in the final products.

3.5.2 | Dietary exposure estimation

The Panel accepted the evidence provided as sufficient to conclude that the residual amounts of food enzyme–TOS in the final FOS products is negligible. Consequently, dietary exposure was not calculated.

3.6 | Margin of exposure

Since no toxicological assessment was considered necessary by the Panel, the margin of exposure was not calculated.

[23]Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

[24]Additional data July 2023/Answer 12.

[25]Technical dossier/p. 74.

[26]Technical dossier/p. 74.

[27]Additional data July 2023/Answer 13 and Annex A9.

4 | CONCLUSIONS

Based on the data provided and the removal of TOS during the intended food production process the Panel concluded that the food enzyme inulinase produced with the non-genetically modified *Aspergillus welwitschiae* strain NZYM-KF does not give rise to safety concerns under the intended conditions of use.

5 | DOCUMENTATION AS PROVIDED TO EFSA

Inulinase produced by a strain of *Aspergillus niger* (strain NZYM-KF). March 2015. Submitted by Novozymes A/S.
Additional data July 2023. Submitted by Novozymes A/S.

ABBREVIATIONS

FOS	fructo-oligosaccharides
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LoD	limit of detection
TOS	total organic solids

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2015-00827

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NOTE

The full opinion will be published in accordance with Article 12 of Regulation (EC) No 1331/2008 once the decision on confidentiality will be received from the European Commission.

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